Remarks/Arguments

Applicants have received and carefully reviewed the Final Office Action of the Examiner mailed February 16, 2007. Currently, claims 46-60 remain pending. Claims 46-60 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Claim rejections – 35 USC § 102

On page 2 of the Final Office Action, claims 46-60 were rejected under 35 U.S.C. 102(b) as being anticipated by Olson et al. (USPN 5,906,619). After careful review, Applicant must respectfully disagree.

Turning to claim 46, which recites:

> 46. (Previously Presented) A distal protection assembly, comprising:
>
> an outer sheath having a proximal end, a distal end, and a lumen extending at least in part therethrough;
>
> an inner shaft disposed within the lumen, the inner shaft having a proximal end and a distal end;
>
> a distal protection device disposed at the distal end of the inner shaft;
>
> a manifold coupled to the proximal end of the inner shaft, the manifold including an actuator assembly coupled to the proximal end of the outer sheath and capable of moving the outer sheath relative to the inner shaft; and
>
> wherein the actuator assembly includes a button axially rotatable about an axis parallel or coincident with the axis of the sheath, the button having a gear in engagement with a number of gear teeth on the proximal end of the outer sheath.

During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification". This means that the words of the claim must be given their plain meaning, which is the ordinary and customary meaning, unless the plain meaning is inconsistent with the specification. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention". (See MPEP § 2111). Accordingly, the meaning of "distal protection device" is the meaning as understood by a person of ordinary skill in the art.

Applicant respectfully asserts that a stent, as suggested in the Final Office Action, is not a distal protection device. A distal protection device is a device that is placed downstream of a lesion or diseased portion of the vessel. The present application, which further illustrates this, recites:

> During angioplasty and atherectomy procedures, stenotic debris is often separated from the stenosis and may be free to flow within the lumen of the vessel. If this debris enters the circulatory system, it could block other vascular regions including the neural vasculature or in the lungs. During angioplasty procedures, stenotic debris may also break loose due to manipulation of the blood vessel. Because of this debris, a number of devices termed distal protection devices have been developed to filter out this debris.
>
> Before using a distal protection device, the device will need to be delivered to an area downstream of where treatment will take place. It is important that the device be delivered properly and efficiently. A need, therefore, exists for devices for delivery of distal protection devices.
>
> After an intravascular procedure has been performed, the distal protection device will need to be removed from the vasculature. Because the distal protection devices are typical used in an expanded condition, it may be difficult to remove the device. A need, therefore exists for devices suitable for retrieval of distal protection devices. (Page 1, line 21 – page 2, line 13).

As such, a person of ordinary skill in the art would understand a distal protection device to be a filter, or like device, to help prevent stenotic debris from flowing through the vasculature. A person of skill in the art would not understand a stent to be such as device. Instead, a stent is a device placed in a body vessel to provide support and keep the vessel open. In many instances, a stent can be permanently left in the vessel to provide support. Furthermore, a stent is generally placed at the location of the diseased vessel and is not placed downstream.

In the Final Office Action, the Examiner includes a diagram of a placement of a stent spanning across the opening of a vessel where two vessels merge together. The Applicant respectfully disagrees with the Examiner's diagram as using a stent as a distal protection device for a number of reasons.

First, a stent will typically have relatively large side openings as compared to a filter material. As such, the stent would only stop very large particulate matter while allowing a majority of the particles, which are small, to easily pass through. In essence,

as stent would not accomplish the objective of a distal protection device by filtering out the particulate matter and a stent would be very ineffective.

Second, a stent it generally provided in a vessel for an extended period of time, which, in some cases, it is provided permanently. Placing the stent as illustrated by the Examiner could be very dangerous to the patient. Over time, the stent may prevent large particles from flowing therethrough and the particulate matter may build-up, essentially blocking the vessel, which could have negative impact on the patient.

Third, in this configuration, a stent can not be efficiently delivered for distal protection, as stated in the application is needed for distal protection devices. In the illustrative example by the Examiner, in order to place the stent and then perform an angioplasty and atherectomy procedure, there stent and the devices for the procedure would have to track different vessels. This would make it very inefficient and in contrast to that recited in the present application. Therefore, for at least these reasons stated above, a stent clearly does not anticipate a distal protection device. Thus, for at least these reasons, claim 46 is believed to be not anticipated by Olson et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, claims 47-53, which depend from claim 46 and include significant additional limitations, are believed to be not anticipated by Olson et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 54, which recites:

> 54. (Previously Presented) A distal protection assembly, comprising:
>
> an outer sheath having a proximal end, a distal end, and a lumen extending at least in part therethrough, the proximal end of the outer sheath including a proximal tubular member having a number of gear teeth;
>
> an inner shaft disposed within the lumen, the inner shaft having a proximal end and a distal end;
>
> a distal protection device disposed at the distal end of the inner shaft;
>
> a manifold coupled to the proximal end of the inner shaft, the manifold including an actuator assembly coupled to the proximal tubular member and capable of moving the outer sheath relative to the inner sheath;

wherein the actuator assembly includes a button axially rotatable about an axis parallel or coincident with the axis of the outer sheath, the button having a number of gear teeth in engagement with the gear teeth on the proximal tubular member; and

wherein axial rotation of the button results in movement of the outer sheath relative to the inner shaft.

As can be clearly seen, claim 54 recites, "a distal protection device disposed at the distal end of the inner shaft". Therefore, for similar reasons given above with reference to claim 46, as well as others, claim 54 is believed to be not anticipated by Olson et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, claims 55-59, which depend from claim 54 and include significant additional limitations, are believed to be not anticipated by Olson et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 60, which recites:

60. (Previously Presented) A distal protection assembly, comprising:

an outer sheath having a proximal end, a distal end, and a lumen extending at least in part therethrough, the proximal end of the outer sheath including a proximal tubular member having a number of gear teeth;

an inner shaft disposed within the lumen, the inner shaft having a proximal end and a distal end;

a distal protection device disposed at the distal end of the inner shaft;

a manifold coupled to the proximal end of the inner shaft and including a notch adapted to receive a key formed on the proximal tubular member, the manifold including an actuator assembly coupled to the proximal tubular member and capable of moving the outer sheath relative to the inner sheath;

wherein the actuator assembly includes a button axially rotatable about an axis parallel or coincident with the axis of the outer sheath, the button having a number of gear teeth in engagement with the gear teeth on the proximal tubular member; and

wherein axial rotation of the button results in movement of the outer sheath relative to the inner shaft.

As can be clearly seen, claim 60 recites, "a distal protection device disposed at the distal end of the inner shaft". Therefore, for similar reasons given above with reference

to claim 46, as well as others, claim 60 is believed to be not anticipated by Olson et al. and Applicant respectfully requests withdrawal of the rejection.

On page 2 of the Final Office Action, claims 46-60 were rejected under 35 U.S.C. 102(b) as being anticipated by Gilson et al. (USPN 6,669,716). After careful review, Applicant must respectfully traverse this rejection.

Nowhere does Gilson et al. appear to disclose "a distal protection device disposed at the distal end of the inner shaft", as recited in claims 46, 54, and 60. The Final Office Action asserts that the stent, as taught by Gilson et al., anticipated the distal protection device of claims 46, 54, and 60. However, as discussed above, clearly a stent does not anticipate a distal protection device. Therefore, for at least this reason, claim 46 is believed to be not anticipated by Gilson et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, claims 47-53 and 55-59, which depend from claims 46 and 54, respectively, and include significant additional limitations, are believed to be not anticipated by Gilson et al. and Applicant respectfully requests withdrawal of the rejection.

Claim Rejections – 35 USC § 103

On page 4 of the Final Office Action, claims 46-60 were rejected under 35 U.S.C. 103(a) as being unpatentable over Turovskiy et al. (2002/0128679) in view of either Olson et al. or Gilson et al. After careful review, Applicant must respectfully traverse the rejection.

In the amendment filed December 1, 2006, on pages 13-17, Applicant provided arguments why claims 46-60 are patentable over Turovskiy et al. in view of either Olson et al. or Gilson et al. However, nowhere in the Final Office Action did the Examiner comment on Applicant's arguments. Applicant respectfully requests that if the Examiner is to maintain this rejection, the Examiner provide a response indicating the reasons that the rejection is maintained over Applicant's arguments.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In the Final Office Action and the Office Action mailed September 19,

2006, the Examiner suggests that it would be obvious to modify Turovskiy et al. with Olson et al. or Gilson et al. to prevent inadvertent linear movement of the handle for the protection device or system. However, after careful review, Applicant must respectfully traverse this rejection.

Applicant must respectfully assert that there is no motivation to modify the teachings of Turovskiy et al. with the teachings of Olson et al. or Gilson et al. Turovskiy et al. appears to teach a filter for protection of released particulate matter during an open surgical carotid endarterectomy. However, Turovskiy et al. appears to teach many features to prevent inadvertent movements of the device. To further illustrate this, Turovskiy et al. recites:

> [0062] Another filter/introducer apparatus adapted for use in open surgical carotid endarterectomy is depicted in FIG. 2A. Filter assembly 12 is mounted on the distal end of elongate member 11 and is operable from the proximal end of the elongate member which is attached to mechanism 5 included in filter delivery cartridge 14. The filter is collapsed and retracted into the lumen of introducer when mechanism 5 slides proximally in slot 6 as depicted in FIG. 2B. After the introducer is inserted in the artery, filter assembly 12 is deployed by sliding mechanism 5 distally in slot 6 until it locks in groove 7, thereby fixing the filter in an open state as depicted in FIG. 2A. The distal region of introducer 15 also includes circumferentially enlarged region 19 for placement of a Javid clamp, thereby fixing the introducer within the vessel, minimizing displacement between the introducer and the vessel, and reducing trauma to the vessel. The distal region of introducer 15 is angled relative to its proximal end to facilitate insertion into an artery. Stopper 17 is slideable mounted in the distal region of introducer 15 and can be positioned perpendicular to the longitudinal axis of the filter as depicted in FIG. 2A or parallel to the axis as depicted in FIG. 2B.
>
> [0063] In use, introducer 15, having filter 12 in a collapsed state, is inserted downstream atheromatous lesion 101 after arteriotomy (shown in broken line) as depicted in FIG. 2C. Filter 12 is expanded. Stopper 17, positioned perpendicular to the longitudinal axis of the filter, minimizes displacement of the introducer and filter in the artery. Clamp 21 is placed over region 19 and endarterectomy is performed with or without a shunt. Alternatively, introducer 15 is inserted through an incision downstream lesion 101 prior to arteriotomy as depicted in FIG. 2D. Stopper 17 is positioned parallel to the longitudinal axis of the filter, thereby stabilizing the introducer on the vessel. After endarterectomy, the filter is collapsed and removed with the captured emboli generated during the procedure. (Emphasis added).

As can be seen, Turovskiy et al. teaches the use of a groove (7) that locks the filter in an open state. Additionally, an enlarged region (19) is provided for placement of a Javid clamp (21) for fixing the introducer within the vessel, minimizing displacement between the introducer and the vessel, and reducing trauma to the vessel. In addition, a stopper (17) is positioned perpendicular to the longitudinal axis of the filter to minimize the displacement of the introducer and filter in the artery. Stopper (17) can also be positioned parallel to the longitudinal axis of the filter, thereby stabilizing the introducer on the vessel. Accordingly, Turovskiy et al. teaches many features to prevent inadvertent movements. Therefore, a person of skill in the art would not look to Olson et al. or Gilson et al. to prevent inadvertent movements of the device because the device of Turovskiy et al. already has features to prevent movement. Therefore, Applicant believes claims 46-60 are allowable over Turovskiy et al. in view of either Olson et al. or Gilson et al. and Applicant respectfully requests withdrawal of the rejection.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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